UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA and the STATE OF NEW YORK *ex rel.* Lee M. Mandel, MD, FACS,

Plaintiffs,

v.

James A. Sakr, MD,

Defendants.

QUI TAM COMPLAINT
AND
DEMAND FOR A JURY TRIAL

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. §§ 3729 *et seq.*

Civil Action No. _____

COMPLAINT

1. *Qui tam* Plaintiff Lee M. Mandel, MD, FACS (*Relator*), through his attorneys, brings this Complaint on behalf of the United States and on his own behalf, pursuant to the Federal False Claims Act, 31 U.S.C. § 3730 *et seq.*, and the New York State False Claims Act, N.Y. State Finance Law §§ 187 *et seq.* ("NYSFCA").

2. Under the False Claims Act, a private person may sue in federal district court for himself and for the United States and may share in any recovery. 31 U.S.C. § 3730(b). That private person is a *relator*, and the action that the relator brings is called a *qui tam* action.

3. Relator alleges that Defendant submitted, or caused to be submitted, to U.S. government health care programs false and fraudulent claims for payment.

I. Jurisdiction, Venue, and Parties

4. This Court has jurisdiction under 31 U.S.C. § 3732 and 28 U.S.C. § 1345. Jurisdiction over the state law claims arises under 31 U.S.C. § 3732(b) (jurisdiction over state

claims arising from the same transaction or occurrence as an action under the federal FCA), and 28 U.S.C. § 1367(a) (supplemental jurisdiction).

5. This Court has personal jurisdiction over Defendant because Defendant transacts business and can be found in this district, and Defendant committed acts within this district that violate 31 U.S.C. § 3729. 31 U.S.C. § 3732(a).

6. Upon information and belief, none of the jurisdictional bars in the FCA, 31 U.S.C. § 3730(e), and in the NYSFCA, N.Y. State Fin. Law §190(9) applies to this action.

7. Venue is proper in this district under 31 U.S.C. § 3732(a) and 28 U.S.C. §1391(b) and (c) because Defendant resides and/or transacts business in this district and has committed acts within this district that violate 31 U.S.C. § 3729. Section 3732(a) further provides for nationwide service of process.

8. **Relator Lee M. Mandel** has complied with all procedural requirements of 31 U.S.C. §3730(b)(2).

9. Relator Lee M. Mandel, MD, FACS, has worked in private practice in the field of otolaryngology since 1996. Among his credentials:

- Board Certified by American Board of Otolaryngology - Head and Neck Surgery;
- Board Certified by American Board of Facial Plastic and Reconstructive Surgery; and
- Fellow of the American College of Surgeons.

10. Relator completed his Residency training at Mount Sinai Hospital (1990-1996) in New York City and maintains professional contacts in New York through his ties with Mount Sinai, current and former faculty, co-residents practicing in the tri-state area, and colleagues and co-faculty from scientific meetings.

11. Dr. Mandel is recognized by his peers and others for his expertise and experience in the practice of otolaryngology:

- President, Florida Society of Otolaryngology, since November 2016.
- Member, Patient Advocacy Committee, American Rhinologic Society.
- Chief of Otolaryngology and Facial Plastic Surgery at Weston Outpatient Surgery Center.
- Former Official Sinus and Allergy Specialist and Official Facial Reconstructive Surgeon for the Florida Panthers NHL Hockey Team.

12. Relator is a faculty member and planning committee member of the Open Forum, the annual international otolaryngology conference, held under the auspices of the Foundation for Innovation, Education and Research in Otolaryngology.

13. Relator seeks to stay abreast of professional issues and current advances in his specialty practice. He engages in educational and professional conferences that offer a forum for discussion among practitioners and continuing education. Relator also often communicates with rhinologists, ENTs, and otolaryngologists, who share anecdotal reports of unusual circumstances of importance to those whose practices focus on patients with disorders of the nose, sinuses, and skullbase.

14. **Defendant James A. Sakr, M.D.** ("Sakr"), NPI 1063474153, Medicaid # 00844064, practices medicine in Wellsville, NY in this district.

15. Defendant enrolled in New York's Medicaid program through the NYS Dept. of Health, Office of Health Insurance Programs, Medicaid Management Information System (also known as "eMedNY") in Albany NY.[1]

16. On information and belief, Defendant files Medicaid claims through New

[1] https://www.emedny.org/info/ProviderEnrollment/enrollguide.aspx. *See also* https://www.emedny.org/ProviderManuals/AllProviders/supplemental.aspx#MEVSPM

York's Office of Health Insurance Programs' contractor, Computer Sciences Corporation.

17. Sakr graduated from the American University of Beirut's Facility of Medicine, Beirut, Lebanon in 1977.

18. Defendant identified himself to CMS type as provider type "Otolaryngology," and represents himself to the public as "Specialty: Otolaryngology (ENT)."[2] However, he is *not* Board certified in Otolaryngology, nor is he board certified in any medical specialty. He is *not* a member of the American Rhinologic Society. He does not hold position(s) in his state specialty medical society.

II. The False Claims Act, Medicare, and Medicaid

A. False Claims Acts

19. The Federal False Claims Act prohibits the submission of false or fraudulent claims and false statements so as to obtain or keep federal money. It provides, in pertinent part:

> (1) In general.— Subject to paragraph (2), any person who—
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> * * *
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . ., plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

20. Under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and

[2] https://www.noyes-health.org/noyes-directory-listing/sakr-james-md

64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted from $ 5,500 to $ 11,000 for violations occurring on or after September 29, 1999. For violations that occurred after November 1, 2015, Department of Justice (DOJ) announced increased penalties to between $10,781 and $21,562 per fraudulent claim.[3]

21. The NYSFCA, effective as of August 27, 2010, imposes civil liability on "any person" who:

> (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> ...
> (g) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government; or
> (h) Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a local government, or conspires to do the same.

N.Y. State Fin. Law §§189(1)(a), (b), (g) and (h) [August 27, 2010].

22. The NYSFCA imposes liability on any person violating Section 189 to the state or a local government for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person. N.Y. State Fin. Law §189 and § 189(1)(g)(ii).

23. A relator who prevails in a NYSFCA *qui tam* action is also entitled to receive from the defendant(s) an amount for reasonable expenses, attorneys' fees and costs. N.Y. State Fin. Law §190(7).

24. "Upcoding" is an act of committing fraud by knowingly and intentionally

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[3] https://www.federalregister.gov/documents/2017/02/03/2017-01306/civil-monetary-penalties-inflation-adjustment-for-2017

submitting a claim under an inappropriate diagnostic or procedural code to obtain a higher rate of reimbursement. Upcoding also occurs by changing the procedure code to a code that pays more money.

25. Upcoding violates general Medicare and New York State rules and policies requiring that submitted claims accurately reflect the services rendered. *See e.g.,* HHS Office of Inspector General's "*Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse,*" http://oig.hhs.gov/fraud/PhysicianEducation/ at pp. 9-12 (Explaining the general requirement for billing accurately and specifically warning against upcoding, billing for services not rendered, billing more than once for the same service, and further explaining the requirement to maintain accurate and complete medical records and documentation of the services provided to ensure submitted claims are supported by true and accurate records.).

26. The financial harm caused by upcoding may exceed the cost of the single upcoded claim. For Medicare Part C (managed care) patients and for the many patients who may eventually move from Medicare Parts A and B to Medicare part C, false diagnoses may increase a risk adjustment score which, in turn, increases the government's payments to Part C insurers.

27. Upcoding can harm patients medically and financially. Fabricated medical histories in patients' charts and medical records can forever skew diagnoses and treatment. This may cause a patient to undergo additional diagnostic exams or even cause a subsequent healthcare provider to perform a procedure that might be unnecessary were the patient viewed as lower risk. In addition, a patient may be declined or charged more for long-term care or life insurance due to these false diagnoses.

B. Medicare and Medicaid

28. Medicare, enacted in 1965 under Title XVIII of the Social Security Act, is a third- party reimbursement program that underwrites medical expenses of the elderly and the disabled. 42 U.S.C.§§ 1395 *et seq*. Medicare reimbursements are paid from the federal Supplementary Medical Insurance Trust Fund.

29. Medicare Part B generally covers physician services, including medical and surgical treatment and outpatient treatment and diagnosis. Part B, 42 U.S.C. §§ 1395j *et seq*.; 1395l (payment of benefits). The Medicare claims in this case arise under Medicare Part B.

30. Medicaid is a medical assistance program for indigent and other needy people that is financed by joint federal and state funding and is administered by the states according to federal regulations, oversight, and enforcement. 42 U.S.C. §§ 1396 *et seq*. Each state implements its version of Medicaid according to a State Plan approved by HHS. Within broad federal regulatory and policy guidelines (*see* 42 C.F.R. § 430 *et seq*., and CMS publications), the states determine who is Medicaid-eligible, what services are covered, and how much to reimburse healthcare providers. The states, through intermediaries, also receive healthcare provider claims for program reimbursements, evaluate those claims, make payments to healthcare providers, and present the claims to HHS/CMS for reimbursement of the federal government's share.

31. New York's Medicaid Program was established in 1966. Act of Apr. 30, 1966, ch. 256, 1966 N.Y. Laws 844. By statute, NYDOH administers this program at the state level. N.Y. Pub. Health Law § 201(1)(v). The NYSFCA claims arise under New York's Medicaid program.

32. NYDOH administers the New York Medicaid Program. NYDOH does this through its Office of Health Insurance Programs, located at Corning Tower, Empire State Plaza, Albany, NY 12237. New York Medicaid claims are processed through the New York State Medicaid Management Information System ("MMIS"), also referred to as "eMedNY."

33. Upon information and belief, Computer Sciences Corporation is a private internet technology contractor that, on behalf of NYDOH, processes New York Medicaid claims submitted to MMIS/eMedNY by healthcare providers in New York State.[4] Computer Sciences Corporation processes New York Medicaid claims at offices at 327 Columbia Turnpike Rensselaer, New York 12144.

34. Physicians must enroll in the Medicare program to be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries. 42 C.F.R. § 424.505.

35. Physicians must enroll in New York's Medicaid program to be eligible to receive Medicaid payments. *See* 18 NYCRR 504.1(b) (1) ("Any person who furnishes medical care, services or supplies for which payments under the medical assistance program are to be claimed; or who arranges the furnishing of such care, services or supplies; or who submits claims for or on behalf of any person furnishing or arranging for the furnishing of such care, services or supplies must enroll as a provider of services prior to being eligible to receive such payments, to arrange for such care, services or supplies or to submit claims for such care, services or supplies.").

36. CMS requires that all claims for physician services be submitted on a form

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[4] https://www.emedny.org/contacts/emedny.aspx

CMS-1500 (Health Insurance Claim Form) ("Form 1500") or its electronic equivalent. 42 C.F.R. 424.32 (Basic requirements for all claims).

37. At all times relevant to this action, Defendant submitted, or caused to be submitted, the electronic equivalent of Form 1500 to CMS and NYDOH for reimbursement for services.

38. Form 1500 requires the submitting healthcare provider to include various fields of information prior to reimbursement, including: the date(s) of service; a code for the service(s) provided known as a "Current Procedural Terminology Code" or "CPT Code"); and the rendering healthcare provider's national identification number ("National Provider Identifier" or "NPI") and signature.

39. According to Form 1500's instructions, a provider's signature certifies "that services shown on [the Form 1500] were medically indicated and necessary for the health of the patient and were personally furnished by [the provider] or were furnished incident to [his/her] professional service by [his/her] employee under [his/her] immediate personal supervision."

40. Providers, such as Defendant, submit claims to Medicare by transmitting them to a private carrier or a Medicare Administrative Contractor ("MAC"), which processes the claims on behalf of HHS/CMS.

41. All healthcare providers that submit claims electronically to CMS or to CMS MACs, must certify in their application that they "will submit claims that are accurate, complete, and truthful," and must acknowledge that "all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare

program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *See* Medicare Claims Processing Manual, § 30.2.A.

42. Medicaid claims are also submitted primarily electronically. On information and belief, the eMedNY system, operated by Computer Sciences Corporation at a facility in Rensselaer, New York under contract with NYDOH, is currently and was at relevant times the Medicaid claims processing agent for the New York State Medicaid Program.

43. All healthcare providers that submit claims to the New York State Medicaid Program must certify, among other things, that all statements in the claim are true, accurate, and complete to the best of the provider's knowledge; that no material fact has been omitted; that the provider is bound by all rules, regulations, policies, standards, fee codes and procedures of the NYDOH in Title 18 of the Official Compilation of Codes, Rules and Regulations of New York State and other publications of the Department, including Provider Manuals and other official bulletins of the Department; and that the certifications are true. *See* New York State Medicaid Program: Information For All Providers—General Billing. [5]

44. Under Medicare and New York Medicaid rules and policies, healthcare providers must contemporaneously create and maintain accurate medical records to support the providers' claims for reimbursement. *See e.g.,* CMS MLN Matters Number: SE1022 ("Providers/suppliers should maintain a medical record for each Medicare beneficiary that is their patient. Remember that medical records must be accurately written, promptly

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[5] https://www.emedny.org/ProviderManuals/AllProviders/PDFS/archive/Information_for_All_Providers-General_Billing-2004-01.pdf.

completed, accessible, properly filed and retained."); *see also, e.g.,* New York State Medicaid Program, Information for All Providers, General Policy, version 2004-1 ("Federal Law and State Regulations require providers to maintain financial and health records necessary to fully disclose the extent of services, care, and supplies provided to Medicaid recipients.").

III. The Fraudulent Conduct

45. Otolaryngology is a medical specialty focusing on care and treatment of the ear, nose, and throat. "Otolaryngologists are physicians trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and neck. They are commonly referred to as ENT physicians." http://www.entnet.org/content/patient-health. Otolaryngologists whose practices focus on patients with disorders of the nose, sinuses, and skullbase are also known as rhinologists.

46. Otolaryngologists commonly perform nasal endoscopy, CPT 31231, a *diagnostic* procedure that allows for visual inspection of a patient's sinuses.[6] Otolaryngologists typically perform this procedure in the office, following application of a decongestant and/or local anesthetic, with an endoscope, a thin flexible tube inserted through a nostril and into a patient's sinuses.

47. Routine nasal *endoscopies*, CPT 31231, are one of otolaryngologists' most commonly billed procedures to Medicare. This is because an otolaryngologist who treats patients with disorders of the nose or sinuses must look at the detailed nasal anatomy before

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[6] The American Medical Association developed Current Procedural Terminology codes, universally known as CPT codes. Five-digit CPT codes are the United States' and CMS' standard for how medical professionals document and report procedures and services.

diagnosing and performing procedures on a patient's sinuses.

48. Although Defendant has filed many Medicare claims relating to his patients' sinuses, he rarely charged under code CPT 31231. For example, in 2014, Medicare reimbursed Defendant for only 19 of these routine diagnostic CPT 31231 nasal endoscopies.

A. False Claims for CPT 31233—Puncturing Patients' Mouths

49. CPT 31233 is "a nasal/sinus endoscopy, diagnostic with maxillary sinusoscopy [via inferior meatus or canine fossa puncture]." Unlike CPT 31231, which involves looking through a nostril, CPT 31233 is a diagnostic procedure that allows the physician to view the maxillary sinus by surgically opening a hole through the mouth in the area above the upper teeth or through a hole made along the floor of the nose into the sinus and inserting the endoscope into a patient's sinus. Thus, CPT 31233 requires a "puncture" for that diagnostic.[7]

50. The American Academy of Otolaryngology -- Head and Neck Surgery clarifies that the CPT 31233 diagnostic procedure requires puncturing a hole into the maxillary sinus at the time of the endoscopy.

> Reimbursement: There have been a number of member inquiries on the correct usage of CPT® codes 31233 Nasal/sinus endoscopy, diagnostic with maxillary sinusoscopy (via inferior meatus or canine fossa puncture) and 31235 Nasal/sinus endoscopy, diagnostic with sphenoid sinusoscopy (via puncture of sphenoidal face or cannulation of ostium). Some who perform endoscopic exams after the postoperative global period to view the interior of maxillary or sphenoid sinuses through existing surgically created patent sinusotomies are reporting 31233 or 31235 (or, perhaps both).
> When the physician performs endoscopic exams postoperatively (to view the interior of maxillary or sphenoid sinuses through existing surgically created

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[7] The *inferior meatus* is at the junction of the floor of the nose and the inner wall of the maxillary sinus within the nose. The *canine fossa* is a depression of the face of the maxillary sinus around the root of the front upper teeth.

> patent sinusotomies), the Academy's position is that only CPT code 31231 Nasal/sinus endoscopy, diagnostic, unilateral or bilateral (separate procedure) is appropriate. Our rationale is that *CPT codes 31233 and 31235 require a puncture or trocar cannulation*[8] prior to placing the scope into the sinus. CPT code 31231 is bilateral while the CPT codes 31233 and 31235 are unilateral. *The use of CPT code 31233 or 31235 to report diagnostic sinus endoscopy performed via an existing and patent opening into the maxillary or sphenoid sinus is incorrect.*

http://www.entnet.org/?q=node/679 [Emphasis supplied].

51. Observing and diagnosing sinuses by puncturing the roof of a patient's mouth (CPT 31233) is more invasive than visualizing nasal anatomy through an endoscope inserted through a patient's nostril (CPT 31231).[9]

52. There is nothing inherently fraudulent about performing CPT 31233 when it is medically required. For that reason, the government reimburses healthcare providers providers who certify that they performed the procedure and that it was medically reasonable and necessary.

53. Although Defendant files many Medicare claims relating to his patients' sinuses, he rarely charges Medicare under code CPT 31231. In 2014, Medicare reimbursed Defendant for only 19 of these routine diagnostic CPT 31231 nasal endoscopies.

54. In contrast to Defendant's 19 routine diagnostic CPT 31231 nasal endoscopies performed in 2014, that same year CMS reimbursed him for 253 CPT 31233 (puncture) diagnostics. Defendant sought and received Medicare reimbursement for this procedure far more often than any other procedure.

55. With respect to the need for CPT 31233 and rhinological practices in New

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[8] A trocar is "a sharp-pointed surgical instrument fitted with a cannula and used especially to insert the cannula into a body cavity as a drainage outlet." https://www.merriam-webster.com/dictionary/trocar A cannula is "a small tube for insertion into a body cavity, duct, or vessel." https://www.merriam-webster.com/dictionary/cannula#medicalDictionary.

[9] If a *prior* procedure left an opening, then visualization of the maxillary sinus through the pre-existing puncture is billed using CPT 31231 (not 31233).

York, Relator concluded, based on his experience and knowledge:

- There is no rhinological subspecialty limited to sinuses immediately above the roof of a patient's mouth.
- It is medically reasonable and appropriate for an otolaryngologist to routinely diagnose sinuses through a nostril, rather than by puncturing the roof of a patient's mouth and inserting an endoscope through the puncture; and it is medically unreasonable and inappropriate to routinely and invasively puncture a patient's mouth for a routine diagnostic, especially without first obtaining a CT scan, which is readily available and noninvasive.
- It is medically unreasonable, and below the standards of professional conduct, for an otolaryngologist to limit diagnoses to the sinuses immediately above a patient's mouth (maxillary sinuses).
- There is no "cluster" of symptoms or diagnoses that would make this volume of 31233 procedures medically reasonable or necessary in upstate New York.

56. Based on Relator's experience and expertise in rhinology and otolaryngology, Relator has determined that most or all of Defendant's CPT 31233 claims are false.

57. Although there are circumstances under which CPT 31233 may be medically necessary, Relator's investigation has determined that Defendant's reputation in the professional community of rhinologicists would not have brought about referrals of patients requiring the more invasive, more complex, CPT 31233 procedure.

58. Relator speculates that if Defendant actually performed the number of claimed diagnostic endoscopy procedures, then he either performed unnecessary invasive procedures on unsuspecting patients or upcoded the routine CPT 31231 diagnostic endoscopy to reflect more expensive CPT 31233 claims.

59. In 2014 for example, CPT 31233 procedures yielded Defendant an additional $137 per procedure from Medicare. Medicare reimbursed Defendant $152 for each of his CPT 31231 claims, but $289 for the claimed CPT 31233s.

B. False Claims for CPT 31237—Endoscopic Debridement

60. CMS shows CPT 31237 as a Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure) and 31237-50 [collectively "31237"].[10]

61. The American Academy of Otolaryngology -- Head and Neck Surgery lists the following clinical indicators for CPT 31237:

1. History (one or more required after failure of mechanical therapy)
   a) *Postoperative care* of endoscopic sinus surgery
   b) *Postoperative* hemorrhage
   c) *Postoperative* exudate or discharge
   d) Complications of sinus *surgery*
   e) Fungal sinusitis
2. Physical Examination
   a) Complete anterior and posterior nasal examination (rhinoscopy after mucosal decongestion) (one or more required)
      - Significant (early or late) scar formation, particularly in the region of the middle meatus or the frontal recess
      - Significant granulation, persistent crusting, or polypoid tissue, unresponsive to medical therapy

[Emphasis supplied.][11]

62. In lay terms, debridement is the removal of unhealthy tissue from a wound to promote healing. Mere removal of mucous—even if performed by a skilled otolaryngologist—is not debridement.

63. Relator alleges below that the claimed CPT 31237s were not performed, or if performed, were medically unnecessary, because:

- Defendant did not conduct the prerequisites surgeries, and other physicians did not refer patients to Defendant for postsurgical 31237s; and
- Defendant's patients did not suffer from prerequisite fungal sinusitis.

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[10] Code 31237 is a unilateral procedure, performed on the right or left sinus. Code 31237-50 is for bilateral debridement, performed on both sides, and pays at 150%.

[11] https://www.entnet.org/sites/default/files/Endoscopic-Debridement-CI%20Updated%208-7-14.pdf.

*1. **Lack of preceding surgeries indicate CPT 31237 was not performed***

64. The clinical indicators for CPT 31237 show that a debridement is performed almost always *after surgery*. Unlike CPT 31231 and 31233 endoscopic *diagnostics*, CPT 31237 is *not* a diagnostic tool but a treatment tool.

65. Defendant's 2014 claim data shows 244 CPT 31237 reimbursements for 86 unique patients. But Defendant's Medicare reimbursements show CMS reimbursed him for only 23 surgeries on 23 patients.[12]

66. Even assuming 23 of these 86 patients received medically necessary postsurgical CPT 31237 debridements, it is extremely unlikely that Defendant received referrals from other physicians for the remaining 63 patients for postsurgical debridements. As set forth in greater detail below, the typical, post-operative debridement is done by the physician who performed the surgery—not farmed-out to another ENT.

67. In Relator's professional experience, he has learned *there is no subspecialty of CPT 31237-debridement*. Consequently, there are few, if any, physicians who receive referrals from hospitals or other ENTs who perform sinus-related surgeries. Further, nothing in Defendant's training or credentials would encourage those types of referrals to him.

68. With rare exceptions, such as a physician in a group practice covering for a colleague on vacation, there is no reason to ever debride another physician's patient during the postoperative period. In Relator's professional experience, most physicians would refuse to see another doctor's patient within six months following surgery because of liability issues.

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[12] The 23 total includes 11 reimbursements for ethmoidectomy (31255, Nasal/sinus endoscopy, surgical; with ethmoidectomy, total [anterior and posterior]), and 12 reimbursements for 31276 (Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus).

This is because both referring CPT 31237 debridement to others and accepting CPT 31237 referrals is below the standard of care. [13]

69. In short, it is not realistic nor reasonable to believe that Defendant received numerous CPT 31237 referrals. Because he performed only a small percentage of the surgeries that resulted in CPT 31237 claims, the circumstances belie the validity of the non-post-operative CPT 31237 reimbursement claims.

2. Rarity of fungal sinusitis indicates CPT 31237 not performed

70. Even without surgeries, CPT 31237 reimbursements may be justified following fungal sinusitis. Fungal sinusitis arises generally from one of two causes. First, it could arise from an intense allergic reaction from a fungus trapped in a sinus. This usually requires surgery to open the sinus. Second, and even more uncommon, is a nonallergic very aggressive fungal sinusitis which occurs in immunocompromised patients.

71. In Relator's professional knowledge and experience, fungal sinusitis is rare. Had there been any fungal sinusitis cluster or epidemic in upstate New York, Relator would have learned of this from discussions in private meetings with colleagues when he attended rhinological and other professional meetings.

72. Further, because Relator practices medicine in South Florida he has significant experience with mold and fungus. He knows from medical experience that sinus problems related to fungus are unusual in the region in which Defendant practices medicine.

73. Based on Relator's experience, knowledge, investigation, and general

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[13] While low quality of care may or may not result in false claims, Relator is not alleging false claims based on quality of care. Rather, based on Relator's knowledge and professional experience, there is no widespread lack of professional standards in rhinological care in the area in which Defendant practices that would support the high volume of CPT 31237 referrals.

knowledge of unusual phenomena dealt with by other rhinologists, ENTs, and otolaryngologists, Relator determined there was no "cluster" or epidemic of fungal sinusitis that would support the volume of CPT 31237 procedures claimed by Defendant.

74. Consequently, the submitted CPT 31237s are false because Defendant claimed reimbursement for these procedures despite the fact that they were neither medically reasonable nor necessary.

c. Relator uncovered the fraudulent conduct.

75. The allegations or transactions herein were not publicly disclosed. Relator is an original source of the information on which his allegations are based within the meaning of the FCA and the NYSFCA. To the extent there were any qualifying public disclosures, Relator's allegations materially add to any information contained in any such public disclosures.

76. The Centers for Medicare and Medicaid Services (CMS) disclose hundreds of databases. Some are available online and others may be ordered from CMS. https://data.cms.gov/

77. CMS disclosed claim data through the "Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File." This data is based on information from CMS's National Claims History Standard Analytic Files. It contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population.[14]

78. Each year's PUF database contains more than 242 million entries relating to a

[14] http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html as of October 10, 2014.

single year's Medicare part B claims. However, this raw data does not reveal the alleged frauds. In particular:

i. It does not disclose total amounts billed by or paid to any particular provider.
ii. It does not compare providers by amounts billed, amounts paid, procedures performed, or otherwise.
iii. It does not disclose medical relationships between procedures.
iv. It does not reveal procedures *not* performed that should have been performed.

79. Relator's expertise and knowledge of the relationship between the particular medical procedures and diagnostics discussed herein gives him the knowledge, skills, and experience to analyze Defendant's medical billing data and Medicare claims data and to make strong inferences resulting in the allegations in this Complaint.

80. For certain analyses, Relator used his professional knowledge and skills to guide the selection and aggregation of certain codes (for example 31231, 31233, 31235, and 31227) for the statistical analyses of these code aggregates. Then, using these figures—which were not revealed by CMS— and based on statistical analysis of millions of records—he applied his medical knowledge, skills, and experience to the data.

81. Data on which Relator based his analysis also included "Shared Patient Data Sets," which CMS has released for 2009 through 2015, in 30-, 60-, 90- and 180-day intervals. This is an even more voluminous data set. For example, one database (30 days) for a single year (2014) contained 55,779,669 records.

82. Relator supported his medical conclusions with the combined 9+ million record part B data and the 55+ million records from the shared patient data set. Because there is nothing inherently fraudulent with performing CPT 31233 or 31237, data resulting from this analysis and synthesis support these allegations but, by itself, this data did not

"disclose" the allegations herein.[15]

D. Count I: Violations of 31 U.S.C. § 3729(a)(1)(A)

Plaintiff repeats and realleges the paragraphs 1- 82 above as if fully set forth herein.

83. Defendant knowingly presented or caused to be presented false or fraudulent claims for payment or approval to Government Health Care Programs, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

84. The United States paid said claims and has sustained damages because of these acts by the Defendant.

E. Count II: Violations of 31 U.S.C. § 3729(a)(1)(B)

Plaintiff repeats and realleges paragraphs 1- 82 above as if fully set forth herein.

85. Defendant knowingly made, used or caused to be made, or used false records or statements material to a false or fraudulent claim, all in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

86. The United States paid said claims and has sustained damages because of these acts by the Defendant.

F. COUNT III: New York False Claims Act Violations

Plaintiff repeats and realleges paragraphs 1- 82 above as if fully set forth herein.

87. On information and belief, in connection with claims submitted to the New York Medicaid Program and the United States, Defendant: (i) knowingly presented, or caused to be presented a false or fraudulent claim for payment or approval; (ii) knowingly made, used or caused to be made or used, a false record or statement material to a false or

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[15] Relator has not included this information as an exhibit. The smaller (9 million record) part B file would require 27 million pages. If printed, 5,400 standard cartons. Stacked four high, and lined end to end, the cartons would stretch 6 1/2 football fields (1,969 feet).

fraudulent claim; (iii) knowingly made, used or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government; and (iv) knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the state or a local government, or conspired to do the same, all in violation of N.Y. State Fin. Law §§189(1)(a), (b), (g) and (h) [effective August 26, 2010].

88. On information and belief, the State of New York has paid money to the Defendant upon the false, fictitious, or fraudulent claims described in this complaint and has thereby suffered damages.

89. By reason of the Defendant's violations of the NYS False Claims Act, the State of New York has suffered economic loss.

PRAYER

WHEREFORE, *Qui Tam* Plaintiff Relator Mandel, for the United States, the State of New York, and for himself, prays that judgment be entered against Defendant as follows:

A. For each count, the amount of damages, trebled as required by law, and civil penalties up to the maximum permitted by law,

B. For the maximum *qui tam* percentage share allowed by law and for attorney's fees, costs and reasonable expenses; and

C. For any and all other relief to which Plaintiff may be entitled.

PLAINTIFF DEMANDS A JURY TRIAL.

Dated: September 13, 2017

THOMAS & SOLOMON LLP

By: _____

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